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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,218

10/07/2005

Pierre Douville

GOUD:059US

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EXAMINER

SHEN, BIN

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/528,218

Applicant(s)

DOUVILLE ET AL.

Examiner

Bin Shen

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 23-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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#### **DETAILED ACTION**

The IDS received 3/18/2005, the preliminary amendment received 3/18/2005 have been entered.

#### ***Election***

Applicant's election with traverse of Group I, claims 1-22, in the reply filed on 11/17/2006 is acknowledged. The traversal is on the ground(s) that there is no undue burden in examining Groups I-III inventions. This is not found persuasive because the arguments ("undue burden") are not applicable to lack of unity restriction rules (PCT Rule 13.1). US5312590A teaches the use of a device suitable for measuring the concentration of two related analytes comprising an enzymatic reaction means; a detector; a data processor. Thus, the application lacks unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 23-45 are nonelected and thus are withdrawn from further consideration.

Claims 1-22 are presented for examination on the merits.

#### ***Specification***

1. The abstract of the disclosure is objected to because the abstract must be a single paragraph. Correction is required. See MPEP § 608.01(b). A new abstract on a separate page is required to replace the current abstract, which is the first page of the WO document of the application.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 3, 9, 18 "capable of" does not state what actually occurs.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 7, 9, 12, 14, 17-19, 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunasingham (USPN5312590).

Gunasingham teaches an analyzer (see abstract) for simultaneously detecting and measuring the concentration of two related analytes, said analytes being substrates for a common enzyme, comprising: an enzymatic reaction monitoring component, a detector, a data processor, wherein working electrode and

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auxiliary electrode are composed of platinum, and wherein reference electrode is composed of silver (col. 4, lines 21-24), the components of enzymatic reaction means (col. 9-10, claims 1-2), wherein the buffer solution is phosphates (col. 7, lines 11-12), wherein the enzyme is oxidase (col. 7, line 19), wherein liquid sample is blood, (col. 5, line 34), wherein the support base is composed of plastic (col. 6, lines 27-28), wherein the analyzer is portable or non-portable for use in point-of-care units (col. 5, lines 54-57).

4. Claims 1-3, 7, 9, 12, 14-16, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by et al. (J of Pharm. And Biomedical Analysis 1998;17:1111-1128).

Liden teaches an analyzer (see abstract) for simultaneously detecting and measuring the concentration of two related analytes, said analytes being substrates for a common enzyme, comprising: an enzymatic reaction monitoring component, a detector, a data processor, wherein working electrode and auxiliary electrode are composed of platinum, and wherein reference electrode is composed of silver (page 1113, right column, 2.2.1), the components of enzymatic reaction means (abstract), wherein the buffer solution is phosphates (page 1113, left column, 1<sup>st</sup> full paragraph, line 5), wherein the enzyme is alcohol oxidase (abstract), wherein liquid sample is blood, (page 1114, left column, 2.2.3.).

Therefore, the cited reference is deemed to anticipate the instant claims above.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-22 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Gunasingham in view of Liden.

Gunasingham teaches what is above.

Gunasingham does not teach alcohol oxidase, permeable polymer is polylysine, electron transfer reagents is ferrocene derivatives, enzymatic reaction monitoring component is a disposable/permanent electrode.

Liden teaches what is above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gunasingham by using alcohol oxidase because Liden teach high sensitivity and selectivity are required to distinguish between ethanol and methanol intoxication (end of page 1111 to beginning of page 1112). One would have been motivated to make the modification because Liden teaches the necessity for fast determination of acute intoxication as well as suspected drunk driving (end of page 1111 to beginning of page 1112) and Gunasingham teaches the convince of monitoring (with portable analyzer) (col. 5, lines 56-58), and would reasonably have expected success in view of both Gunasingham and Liden's

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teaching of the both the methods and the importance of detect alcohol/methanol simultaneously. The choices of polylysing as permeable polymer, electron transfer reagents is ferrocene derivatives, enzymatic reaction monitoring component is a disposable/permanent electrode are deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### **Conclusion**

6. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571)

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272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

*R. Gitomer*

*B Shen*

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RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200